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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/026,736	03/05/93	ALIZON	M 3495.0010-12

EXAMINER
PETERSEN, L

18M2/0811

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
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ART UNIT	PAPER NUMBER
1806	6

DATE MAILED: 08/11/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 3/5/93 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449. 5 pages
4. ☒ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 11-16 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1-10 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 11-16 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☒ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☒ been filed in parent application, serial no. 158652; filed on 2/22/88.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 9-89)

UNITED STATES DEPARTMENT OF COMMERCE
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Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE

DATE MAILED:

NOTICE OF INFORMAL APPLICATION

(Attachment to Office Action)

This application does not conform with the rules governing applications for the reason(s) checked below. The period within which to correct these requirements and avoid abandonment is set in the accompanying Office action.

A. A new oath or declaration, identifying this application by the application number and filing date is required. The oath or declaration does not comply with 37 CFR 1.63 in that it:

1. ☐ does not identify the city and state or foreign country of residence of each inventor.
2. ☐ does not identify the citizenship of each inventor.
3. ☐ does not state whether the inventor is a sole or joint inventor.
4. ☐ does not state that the person making the oath or declaration:
   a. ☐ has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
   b. ☐ believes the named inventor or inventors to be the original and the first inventor or inventors of the subject matter which is claimed and for which a patent is sought.
   c. ☐ acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.
5. ☐ does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of its filing.
6. ☐ does not state that the person making the oath or declaration acknowledges the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and filing date of the continuation-in-part application which discloses and claims subject matter in addition to that disclosed in the prior application (37 CFR 1.63(d)).
7. ☐ does not include the date of execution.
8. ☐ does not use permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a).
9. ☐ contains non-initialed alterations (See 37 CFR 1.52(c)).
10. ☒ Other: FIGURE WHAT DESCRIPTION: 19-26

B. Applicant is required to provide:

1. ☐ A statement signed by applicant giving his or her complete name. A full name must include at least one given name without abbreviation as required by (37 CFR 1.41(a)).
2. ☐ Proof of authority of the legal representative under 37 CFR 1.44.
3. ☐ An abstract in compliance with 37 CFR 1.72(b).
4. ☐ A statement signed by applicant giving his or her complete post office address (37 CFR 1.33(a)).
5. ☐ A copy of the specification written, typed, or printed in permanent ink, or its equivalent in quality as required by 37 CFR 1.52(a).
6. ☐ Other:

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. 602.1 and 602.02. The oath or declaration is defective because:

(2). It does not identify the city and state or foreign country of residence of each inventor. As the post office address has been omitted, it must also be supplied.

Claims 11-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject, matter which applicant regards as the invention. Claims 11,13 and 15 part h, are rendered indefinite in the use of the asterics "*". It is not clear what is meant by this symbol.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification as originally filed does not provide support for the claimed invention. Claims 11-16 as currently written as an "isolated antibody", a "labelled antibody", "an antibody which binds to an immunological complex" and an immunological complex which comprises an antibody specific for the sequences recited in claim 11 and the individual sequences. The specification on pages 15 and 16, contemplates the production of antibodies against the disclosed peptides. However, there is no description of isolating or labelling such antibodies. Although such practices (isolation and labelling of antibodies) are routine

in the art, there is no literal support for either isolated or labelled antibodies. Furthermore, the claims as written are drawn to antibodies which bind to a peptide represented by the sequences of ORF-Q, ORF-R, ORFs 1-5 and LTR as set forth in claim 11 for example. The specification on pages 12 and 13 delineates the boundaries of the different ORFs which presents a discrepancy between the nucleotide sequence stated in the specification. For example, ORF 1 is said to start at nucleotide sequence 5029, and end at 5316, whereas in the claim ORF 1 begins at 5031 and ends at 5316. Also ORF 2 is said to start at nucleotide sequence 5273 and end at 5515, whereas in the claims ORF 2 begins at nucleic acid 5274 and ends at 5514, ORF 3 is said to start at 5383 whereas in the claim it starts at 5384 and etc. (see figures 8 and 9). Furthermore, the boundaries of the LTR as set in the original specification are different from the sequence of the LTR presented in the claims and therefore it is unclear to which region of the figure, the sequence of the LTR corresponds. The disclosed boundaries for the ORFs and the LTRs appears to be different from those which are recited within the claims and therefore, there is no support for the invention as is currently claimed.

The claims also read on antibodies specific for an amino acid sequence of HIV-1 type 1, however, the specification does not mention this language at all. The specification has shown the cloning and sequences of LAV, which is a specific strain of HIV.

It is doubtful that the antibodies specific for an ORF or LTR of one strain of HIV can detect the presence of another different strain of HIV, since the ORFs of the different viruses differ in starting points. The difference in sequence and open reading frames of differing strains of HIV is made clear by the Ratner et. al. article which shows a different amino acid sequence and ORF for the HTLV-III strain than that which is disclosed in the specification.

Claims 11-16 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

35 U.S.C. § 101 reads as follows:

> **Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.**

Claims 11-16 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

The claims are drawn to an isolated antibody which binds to specific amino acid sequences of HIV open reading frames (ORFs). A disclosed utility of the antibodies is for use as diagnostic reagents in order to detect the presence of HIV proteins (see specification top of page 16). There is no indication in the specification that the peptides which are recited are natural HIV proteins, eg. that they are translated into proteins and that they

would be expressed in an HIV infected individual. In many instances open reading frames are not translated into proteins in the appropriate in vivo system, thus the ORFs of the HIV which are recited may not be functional or secreted proteins of the HIV. The ORFs may encode proteins which can be expressed in an artificial system, such as a transfected cell line but may be quite dormant in an infected cell. If such proteins are not typical products of HIV infection, than antibodies against such peptides would have no diagnostic value whatsoever. Furthermore, even if said peptides were present in HIV infected individuals, the epitope against which the antibody is directed must be unique to the specie which is to be detected. In other words, a cross reactive antibody, eg. one that reacts with self proteins or other pathogens which may have similar sequences, would also be of no diagnostic value. Arya et. al. compare the sequences of AIDS associated virus with the genomes of at least two human T cell leukemia viruses (HTLV-I and HTLV-II), it is interesting to note that there is a great degree of homology between the three genomes in all regions except for the LTRs. This does not necessary mean that antibodies to LTRs will be diagnostically effective since, the amino acids sequence of the LTR may be similar to other proteins. It would appear that there is no support in the specification that the claimed antibodies have the asserted utilities for diagnostic applications for the reasons set forth above. It should also be noted that there is no disclosed

utility whatsoever for the claimed complex, comprising the antibody and the peptides (claims 15-16).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lila Feisee whose telephone number is (703) 308-2731.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO FAX Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 FAX Center number is (703) 308-4227. The hours of operation of the Center are 8:45 am - 4:45 pm, Monday - Friday.

Feisee/lf
August 3, 1993

Y. CHRISTINA CHAN
PRIMARY EXAMINER
GROUP 180